

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK**

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SHIRE CANADA INC, SHIRE INTERNATIONAL : Docket No. 11 civ 0233 (PGG)
LICENSING B.V., AND SHIRE US INC.

Plaintiffs,

- v. -

ALKEM LABORATORIES, LTD.

Defendant.
-----X

**MEMORANDUM OF LAW IN SUPPORT OF DEFENDANT
ALKEM LABORATORIES, LTD.'S MOTION TO DISMISS
OR, IN THE ALTERNATIVE, FOR SUMMARY JUDGMENT**

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Rule 12(d)1

Defendant Alkem Laboratories, Ltd. ("Alkem") of Mumbai, India, respectfully submits this Memorandum of Law in support of its Motion to Dismiss the Complaint under Federal Rule of Civil Procedure 12(b)(2) for lack of personal jurisdiction. In the alternative, since discovery has been taken on this issue, Alkem's motion may be treated as one for summary judgment under Rule 12(d).

INTRODUCTION

Alkem is an Indian company with no contacts in this State. It does not have an office in New York. (Deposition of Jonathan B. Rome ("Rome Deposition"), Exhibit ("Ex.") F to Declaration of Jacqueline M. Russo ("Russo Dec."), at 338.) It does not have employees, officers, or agents in New York. (*Id.* at 340.) Alkem does not direct marketing efforts to New York residents. (*Id.*) There is no personal jurisdiction in this State as to Alkem.

All but conceding this fact, Plaintiffs filed on the same day as they filed this action a virtually identical lawsuit in the State of Illinois. (Russo Dec. at ¶ 4.) This is because Alkem named as an agent for purposes of this action an attorney in Illinois, and that is the basis for Plaintiffs' jurisdiction there. (*Id.* at ¶ 3, Ex. A.) Counsel for Alkem even warned Plaintiffs, before they filed suit, that there is no jurisdiction in this State, and that Alkem would not consent to be sued here, hoping to avoid unnecessary motion practice. (*Id.* at ¶ 2.) Alkem provided alternatives, including its willingness to consent to jurisdiction in New Jersey, Delaware, or Washington D.C. for purposes of this action, and of course it had a registered agent for purposes of this action in Illinois. (*Id.*) Alkem's lack of contact with New York mandates that the court dismiss this suit for lack of jurisdiction. Apart from jurisdictional grounds, this suit should also be transferred to Illinois under the venue statute, where the same litigation with the same asserted claims is already underway.

FACTS

Alkem is an Indian pharmaceutical company with its principal place of business in Mumbai, India. (*Id.* at ¶ 8, Ex. F at 337-38.) On December 1, 2010, Alkem filed an Abbreviated New Drug Application (“ANDA”) with the U.S. Food and Drug Administration, seeking its approval to market a generic version of the drug known as lanthanum carbonate. (*Id.* at ¶ 3.) Alkem also notified Plaintiffs Shire International Licensing BV (a company in the Netherlands), Shire Canada (a company in Canada), and Shire US (a company in Pennsylvania, USA) that Alkem had submitted this ANDA. (*Id.*) That notification identified an agent in Illinois, a lawyer at Winston & Strawn’s Chicago office, to accept service of process on behalf of Alkem in connection with this ANDA. *Id.*

On January 11, 2011, Plaintiffs filed a patent infringement action against Alkem in this Court under 35 U.S.C. § 271(e)(2)(A). (*Id.* at ¶ 3.) In their complaint, Plaintiffs allege that Alkem infringed two U.S. patents related the lanthanum carbonate: 5,968,976 and 7,465,465. (*Id.*) The basis for the lawsuit is that Alkem filed its lanthanum carbonate ANDA with the FDA, and that the submission of this document was an act of infringement. Plaintiffs’ claims arise under the Hatch-Waxman Amendments to the Federal Food, Drug and Cosmetic Act (the “Hatch-Waxman” Act). Under the Hatch-Waxman Act, a pharmaceutical company may file an ANDA for FDA approval to market a generic version of a previously-approved drug. In enacting the Hatch-Waxman Act, “Congress sought to get generic drugs into the hands of patients at reasonable prices—fast.” *In re Barr Labs, Inc.*, 930 F.2d 72, 76 (D.C. Cir. 1991). To achieve this goal, the Hatch-Waxman Act created the ANDA procedure and “a mechanism to facilitate the adjudication of claims of infringement of patents relating to the innovator’s drugs” before the generic drug is marketed. *Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1358

(Fed. Cir. 2003). The Hatch-Waxman Act allows a patent holder to treat an ANDA-filer's submission of a Paragraph IV certification, without more, as an act of infringement. *See* 35 U.S.C. § 271(e)(2)(A). Alkem does not market or sell lanthanum carbonate in the US because it does not yet have FDA approval to do so.

It is not surprising that Plaintiffs sought to bolster their claim through discovery. That discovery, which Plaintiffs have now received, does not change the underlying jurisdiction facts and provides no support for plaintiffs' legally insufficient jurisdictional case. The only basis Plaintiffs actually identify in support of their claim for personal jurisdiction is the assertion that Alkem "purposefully availed itself of the rights and benefits of New York law" by "purposefully directing product sales and marketing efforts toward New York and the United States." *See* Complaint at ¶ 6. Plaintiffs mere assertion of a legal conclusion and failure to provide any facts that would warrant the jurisdiction of Alkem support the rightful dismissal of Plaintiffs' complaint on jurisdictional grounds.

At the time Plaintiffs commenced this action and continuing until today, Alkem is an Indian company located in Mumbai, India. (Russo Dec. ¶ 8, Ex. F at 337-38.) Alkem is not incorporated in New York nor registered to do business here. (*Id.* at 338.) Alkem has no offices in New York nor a place of business within the State. (*Id.*) Alkem neither owns nor rents property or office space in New York. (*Id.* at 340.) Alkem has no employees, officers, or agents in New York. (*Id.*) Alkem does not purposefully direct marketing efforts or sales pitches to New York residents. (*Id.* at 338.) Alkem does not have any bank account or other property in New York. (*Id.* at 340.) As for the specific lanthanum carbonate drug at issue in this case, there is not even an allegation that Alkem sells it anywhere in the United States, much less in New York. Alkem has no contractual agreements with New York entities or residents. (*Id.* at 340.)

Alkem simply does not direct its activities toward New York nor avail itself of any benefits from New York. (*Id.* at 301.) There are no contacts warranting personal jurisdiction here.

Yet Alkem does have contact with other states as it relates to the underlying cause of action. Specifically, Alkem named counsel in Illinois as its agent for receiving notice in connection with the very ANDA application alleged to infringe, for lanthanum carbonate chewable tablets. (*Id.* at ¶ 2.) In fact, the person Plaintiffs served with the New York complaint was the very same agent for service in Illinois, a Winston & Strawn LLP attorney in Chicago. Plaintiffs even hired a process server to try to manually effect service in Illinois. Plaintiffs also filed a virtually identical suit in the Northern District of Illinois, and alleged jurisdiction was proper there precisely because “Alkem named Imron T. Aly of the Chicago office of Winston & Strawn LLP as its agent for acceptance of service of process.” (*Id.* at ¶ 4.) The Illinois action should proceed on course.

Alkem’s connections to the United States as a whole are very limited. REDACTED

Ascend is a pharmaceutical product distribution company located in New Jersey. (Russo Dec. ¶ 8, Ex. F at 12, 342.) Ascend does not have offices in New York. (*Id.* at 342.) Unlike Alkem, Ascend does not manufacture any products. (*Id.* at 122.) Alkem does not tell Ascend how to market or distribute any product. (*Id.* at 53-54.) Though the complaint in this case was filed in January 2011, Ascend did not start selling any Alkem product until February 2011. (*Id.* at 89-90.) Even today, Ascend sells only

¹ Alkem is willing to stipulate, for purposes of this motion, REDACTED, but only under the condition that Plaintiffs agree discovery is complete. Plaintiffs filed a letter with the Court on Friday, April 29, seeking even more discovery, and if additional discovery is obtained, then Alkem reserves the right REDACTED

three Alkem products (not lanthanum carbonate). (*Id.* at 187-188.) Ascend purchases pharmaceutical products from various manufacturing companies and resells them at a profit. The products are obtained through a purchase order, where Ascend buys product from Alkem, and then sells it independently. (*Id.* at 307.) This is done without Alkem telling Ascend where to sell or for how much. (*Id.* at 339.) Both before the Alkem involvement, and through today, Ascend distributes pharmaceutical products for several companies other than Alkem. (*Id.* at 122.) Alkem does not tell Ascend how to market or distribute products. (*Id.* at 340.)

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Ascend does not seek permission from Alkem before selling pharmaceutical products to a customer. (*Id.* at 343.) Ascend is not registered to do business in New York and has no agent here, but because of its business in pharmaceuticals, Ascend had a pre-existing “out of state wholesaler” listing in New York and was part of New York’s low income pharmaceutical reimbursement program. (*Id.* at 163, 344-45.) Ascend is not a defendant in this case, Alkem is. Alkem does not know where Ascend ships its drugs. (*Id.* at 346.) When Alkem traveled to the United States to meet with Ascend, it did so in New Jersey, and traveled in and out of Newark Airport with one exception: one of Alkem’s employees flew out of New York’s JFK airport so he could visit the Statue of Liberty. (*Id.* at 341.)

ARGUMENT

This case should be dismissed because Plaintiffs cannot meet their burden of establishing that this Court has either specific or general personal jurisdiction over Alkem. *See Hvide Marine Int’l Inc. v. Employers Ins. of Wausau*, 724 F. Supp. 180, 182 (S.D.N.Y. 1989) (“[t]he burden of ultimately establishing personal jurisdiction over a defendant is upon the plaintiff.”) For the reasons explained below, the conclusory allegations in Plaintiffs’ Complaint fail to support even

a *prima facie* case for personal jurisdiction, and nothing in the jurisdictional discovery Plaintiffs requested and have now received changes that. Now that Plaintiffs have taken and received discovery, Plaintiffs must meet the “stricter preponderance of the evidence standard.” *Id.*

Plaintiffs will undoubtedly argue—though they did not so plead—that there is no jurisdiction as to Alkem,

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could be subject to personal jurisdiction in New York. There are many problems with this argument. Alkem’s 2010 acquisition of a subsidiary (see *supra* fn.1) that began facilitating the sale in New York of certain Alkem products (excluding, of course, the drug at issue in this suit, which Alkem does not sell anywhere in the United States) does not provide the requisite jurisdictional hook. Specific jurisdiction applies only when the specific legal claims in the suit “arise out of or relate to” the defendant’s forum contacts, a connection Plaintiffs do not (and cannot) allege. Plaintiffs’ allegations of patent infringement relate not to the sale or use of any drug, but only to the filing of a paper application to the FDA (also not in New York).

The test for *general* jurisdiction, which is the only jurisdictional basis Plaintiffs assert, is much more demanding because a “stream of commerce” analysis is not enough. *See, e.g., Metro. Life Ins. Co. v. Roberston-Ceco Corp.*, 84 F.3d 560, 568 (2d Cir.), cert. denied 519 U.S. 1006-07 (1996) (“[b]ecause general jurisdiction is not related to the events giving rise to the suit, courts impose a more stringent minimum contacts test.”)

The reason is clear. General jurisdiction would allow courts in the forum state to exercise their power over the defendant over any claims relating to the defendant’s activities anywhere in the world. Accordingly, it requires a showing that the defendant has a significant, domiciliary-like presence in the forum State. Specifically, it requires a showing the defendant “ha[s] been

‘carrying on in the [the forum State] a *continuous and systematic . . . part of its general business*’.” *Helicopteros Nacionales de Colombia v. Hall*, 466 U.S. 408, 413-14 (1984) (quoting *Perkins v. Benguet Consol. Mining Co.*, 342 U.S. 437, 438 (1952)) (emphasis added). Like the United States Supreme Court, New York courts have repeatedly held that this test is not met simply because a foreign defendant markets or sells products in a foreign state through third parties or affiliates, and have reached this conclusion even in cases where—unlike here—the defendant has some physical contacts with the forum. The reason is a sound and powerful one. If the “injection of products into the stream of commerce” showing that is sometimes sufficient to support *specific* jurisdiction were also enough to support far broader *general* jurisdiction, which as discussed below is rooted in the premise that a defendant has a presence in the forum akin to that of a domiciliary, the centuries-old distinction between the two types of jurisdiction would collapse. New York in particular takes this distinction very seriously, because otherwise “it would not be difficult for [any] plaintiff suing a multinational foreign corporation in the federal courts in New York.” *In re Ski Train Fire in Kaprun, Austria on Nov. 11, 2000*, 230 F.Supp. 2d 403, 413 (S.D.N.Y. 2002) (quoting *Jazini*, 148 F.3d 181, 185 (2d Cir. 1998)) (dismissing Siemens Austria for lack of personal jurisdiction, despite its connection to and the conceded personal jurisdiction in New York of Siemens Germany.)

I. Standard Of Review Governing Dismissal for Lack of Personal Jurisdiction

Alkem moves to dismiss Plaintiffs’ Complaint under Fed. R. Civ. P. 12(b)(2) for lack of personal jurisdiction. A lawsuit that relates to patent infringement is governed by the laws of the Federal Circuit. *Hildebrand v. Steck Mfg. Co., Inc.*, 279 F.3d 1351, 1354 (Fed. Cir. 2002). However, in assessing whether a court has personal jurisdiction over a defendant, “federal courts apply the relevant state statute.” *Aqua Prods., Inc. v. Smartpool, Inc.*, No. 04-CV-5492, 2005 WL 1994013, at *2 (S.D.N.Y. Aug. 18, 2005); *see also Graphic Controls Corp. v. Utah Med.*

Prods., Inc., 149 F.3d 1382, 1386 n.2 (Fed. Cir. 1998) (“Federal courts apply the relevant state statute when determining whether a federal court, sitting in a particular case, has personal jurisdiction over a defendant, even when the cause of action is purely federal”) (citing Fed. R. Civ. P. 4(k).) Moreover, the Federal Circuit will “defer to the interpretations of the relevant state and federal courts, including their determinations regarding whether or not such statutes are intended to reach the limit of federal due process.” *Id.* at 1385. New York law is the relevant state statute in this case.

Plaintiffs bear the burden of establishing this Court’s personal jurisdiction over Alkem. *Whitaker v. Am. Telecasting, Inc.*, 261 F.3d 196, 208 (2d Cir. 2001). To survive a motion to dismiss, even without discovery, Plaintiffs must have made a *prima facie* showing of facts sufficient to support a finding of personal jurisdiction. “[W]here defendant rebuts plaintiffs’ unsupported allegations with direct, highly specific, testimonial evidence regarding a fact essential to jurisdiction – and plaintiffs do not counter that evidence – the allegation may be deemed refused.” *Merck & Co., Inc. v. Mediplan Health Consulting, Inc.*, 425 F. Supp. 2d 402, 420 (S.D.N.Y. 2006) (citation omitted). Now that Plaintiffs have been awarded and received discovery, however, they must satisfy the “stricter preponderance of the evidence standard.” *Hvide Marine*, 724 F. Supp. at 182.

Alkem is neither a resident of, nor a registered corporation in, the State of New York. (Russo Dec., Exhibit F at 338.) Therefore, “[t]o determine whether it may exercise personal jurisdiction over a non-domiciliary, a district court engages in a two-part analysis. *First*, the court must determine whether jurisdiction exists under the law of the forum state, here, New York. *Second*, the court must determine whether the exercise of personal jurisdiction under state

law satisfies federal due process requirements.” *Merck*, 425 F. Supp. 2d at 419 (emphasis added). These tests are discussed in the sections below.

II. NEW YORK’S LONG ARM STATUTE DOES NOT REACH ALKEM

There is no jurisdiction under New York law. Under the New York Civil Practice Law and Rules (“CPLR”), personal jurisdiction can be established in one of two ways: (1) general personal jurisdiction based on the habitual and systematic conduct of business within the State; and (2) specific personal jurisdiction based on engaging in certain activities within the district that give rise to the specific cause of action. *See* CPLR 301 and 302. Alkem is not subject to personal jurisdiction in New York on either basis.

A. **Alkem Is Not Subject To Specific Jurisdiction Under New York Law**

Because specific personal jurisdiction is not and cannot be plead (as lanthanum carbonate was not made or sold here, or anywhere in the United States), that is addressed first and readily dismissed. Specific jurisdiction exists where the claims in a particular case arise directly from the defendant’s alleged contacts with the forum, *i.e.*, where there is “a substantial nexus between the cause of action and the defendant’s contacts with New York.” *Graphic Controls*, 149 F.3d at 1386; *see also Sole Resort, S.A. de C.V. v. Allure Resorts Mgmt., LLC*, 450 F.3d 100, 103 (2d Cir. 2006) *aff’d*, 2008 WL 4643787 (2d Cir. Oct. 20, 2008) (citation omitted) (plaintiff must demonstrate “some articulable nexus between the business transacted and the cause of action sued upon.”) That straightforward test is plainly not met here, since Lanthanum Carbonate not sold anywhere in the US, and a cursory review of the relevant CPLR provisions confirm no specific jurisdiction here.

CPLR Section 302(a), which governs specific jurisdiction over non-domiciliaries, has four parts, none of which applies here. “For a court to assert jurisdiction over a defendant under [the first part], section 302(a)(1), the plaintiff must meet the following two prong test: (1) the

defendant's business activities in New York must be activities by which the defendant projects itself into New York in such a way as to purposefully avail itself of the benefits and protections of New York laws and (2) the plaintiff's cause of action must *arise out of* that business activity within the state.” *Graphic Controls*, 149 F.3d at 1386 (emphasis added) (citing N.Y. Civ. Prac. § 302(a)(1) (McKinney 1990).) Neither prong is met here. *First*, as discussed above, Alkem itself does not conduct any activity in New York, nor has it targeted any business efforts to this State. As such, Alkem cannot be said to have purposefully availed itself to the benefits and protections of New York laws. *Second*, and regardless (*i.e.*, even if the indirect New York contacts Plaintiffs allege were sufficient to establish that Alkem conducted some activity in New York), there is no nexus between Plaintiffs’ cause of action and those alleged contacts. It is undisputed that Plaintiffs’ claims relate to Alkem’s ANDA, which was filed in Silver Spring, Maryland, named an agent in Illinois, and concerned a drug that Alkem does not currently produce or sell anywhere in the United States. Accordingly, the New York contacts that Plaintiffs allege, even if adequately pled, could not support specific jurisdiction under Section 302(a)(1). The same is true under the three remaining parts of Section 302(a). Indeed, these subsections foreclose jurisdiction for the additional reason that they are limited to circumstances that Plaintiffs do not even attempt to plead here. *See* N.Y. Civ. Prac. § 302(a)(2) (tortious acts within the State); 302(a)(3) (acts causing personal injury within the State); 302(a) (4) (acts by defendant that owns, uses or possesses real property in the State) (McKinney 1990)); *see generally* Russo Dec., ¶ 8, Ex. F (Alkem does not own, use or possess any real property situated within New York.)

B. Alkem Is Not Subject To General Jurisdiction Under New York Law

Plaintiffs similarly cannot establish the (far more demanding) proposition that Alkem is subject to general jurisdiction in New York. New York courts look to several factors to determine whether a foreign defendant is subject to general jurisdiction. None is present here.

Under CPLR 301, for a foreign defendant, such as Alkem, to be subject to general personal jurisdiction within the forum, the defendant's business contacts with the forum must be so extensive that they may be described as "continuous and systematic," enough to show that the corporation is "doing business" in New York in the sense historically required to establish a corporate "presence" in the State. *Koehler v. Bank of Bermuda Ltd.*, 101 F.3d 863, 865 (2d Cir. 1996) (quoting *Frummer v. Hilton Hotels Int'l, Inc.*, 19 N.Y.2d 533, 536, 281 N.Y.S.2d 41, 43 (1967) ("a foreign corporation is subject to suit in New York state courts if it is 'engaged in such a continuous and systematic course of "doing business" here as to warrant a finding of its 'presence' in this jurisdiction")); see also *Landoil Res. Corp. v. Alexander & Alexander Servs., Inc.*, 77 N.Y.2d 28, 33-34, 563 N.Y.S.2d 739, 742 (1990) (the defendant must be doing business "not occasionally or casually, but with a fair measure of permanence and continuity".)

Because the question OF whether a foreign defendant is "doing business" in New York for jurisdictional purposes "boils down to 'presence'," *Arquest, Inc. v. Kimberly-Clark Worldwide, Inc.*, No. 07 Civ. 11202, 2008 WL 2971775, at *5 (S.D.N.Y. July 31, 2008), courts must consider the circumstances in which forum contacts have been deemed sufficient to establish such presence. In large part because the presence requirement derives from cases upholding jurisdiction over defendants with significant *physical* operations in the forum, "[p]resence" has been interpreted to mean "substance, continuity, regularity and permanence at the time the action is brought." *Overseas Media Inc. v. Skvortsov*, 407 F. Supp. 2d 563, 568 (S.D.N.Y. 2005) *aff'd*, 277 F. App'x 92 (2d Cir. 2008) (quoting Weinstein, Korn & Miller, New York Civil Practice: CPLR ¶ 301.16 (2005).) Courts assessing whether a foreign defendant has established this type of "presence" typically assess four factors: "(1) the existence of an office in New York; (2) the solicitation of business in state; (3) the presence of bank accounts and other

property in the state; and (4) the presence of employees of the foreign defendant in the state.” *Hoffritz for Cutlery, Inc. v. Amajac, Ltd.*, 763 F. 2d 55, 57 (2d Cir. 1985) (numbers added); *Cornell v. Assicurazioni Generali S.p.A., Consol.*, No. 97 Civ. 2262, 2000 WL 284222, at *2 (S.D.N.Y. Mar. 16, 2000).

None of Alkem’s activities fall into any of these categories as defined by New York law. Specifically:

- 1) Alkem has no office in New York.
- 2) Alkem does not solicit business in New York.
- 3) Alkem does not retain any bank accounts or other property in New York.
- 4) Alkem does not keep employees in New York.

(*See generally* Russo Dec., ¶ 8, Ex. F.) Under the controlling cases discussed below, these facts establish that Alkem’s actions do not, alone or in the aggregate, amount to the “continuous and systematic course of doing business” necessary to subject a non-domiciliary to general jurisdiction in the State of New York. *See, e.g., Sandoval v. Abaco Club of Winding Bay*, 507 F.Supp. 2d 312, 316 (S.D.N.Y. 2007) (finding that without these four factors, defendant “is not subject to general jurisdiction under CPLR § 301.”)

As noted, Plaintiffs’ entire jurisdictional argument proceeds on the assertion that Alkem:

availed itself of the rights and benefits of New York law, having engaged in substantial and continuing contacts with the State and with the United States, including, but not limited to, purposefully directing product sales and marketing efforts toward New York and the United States.

Complaint at ¶ 6. Plaintiffs cannot rely on these alleged contacts as a basis for general jurisdiction in New York for two independent reasons. *First*, it is well settled that such bare bones, conclusory allegations are insufficient to support even a *prima facie* showing of personal jurisdiction under settled Second and Federal Circuit law. *See, e.g., Jazini v. Nissan Motor Co.*

Ltd., 148 F.3d 181, 184 (2d Cir. 1998) (conclusory statement lacking factual support found insufficient to constitute *prima facie* showing of jurisdiction); *Cornell*, 2000 WL 1099844, at *2 (“legal conclusions couched as factual allegations are not facts and cannot substitute for facts”); *Marcinkowska v. IMG Worldwide, Inc.*, 342 Fed. App’x 632, 635 (Fed. Cir. 2009) (affirming district court finding of “no general jurisdiction over [the defendant] due to a lack of *evidence* of any systematic or continuous contacts with” the forum state) (emphasis added).

Second, Plaintiffs’ allegation that Alkem “purposefully direct[ed] product sales and marketing efforts toward New York,” even if treated as adequately re-pled in light of the recent discovery Plaintiffs have taken, would not support general jurisdiction because such allegations are insufficient to establish the “continuous and systematic” forum contacts that both New York law and controlling Supreme Court precedent requires for the exercise of such jurisdiction. The reason is that the “connection” to the forum state is at best the distribution of Alkem’s products here, but in the most indirect fashion: Alkem manufactures pharmaceutical products in India, and only in 2010 started selling limited product to distribution companies in the United States (but none in New York.) Then the distributor chooses to sell the product to retailers like CVS (which could, but need not, be in New York), and then the retailers sell to customers across the United States (including New York). Such strings of transactions are not enough to support general jurisdiction as a matter of law, even assuming that Alkem is responsible for the business relationships of its non-New York distributors, as discussed further below. *See, e.g., Hvide Marine*, 724 F.Supp. at 185 (“those contacts simply indicate the existence of business relationships with New York entities, not a jurisdictional presence in New York.”)

REDACTED

REDACTED

That relationship, therefore, is not eligible to show continuous and systematic conduct, because it was concluded by the time Plaintiffs filed their lawsuit in January 2011. Relying upon the Breckenridge relationship would run afoul of the many cases emphasizing that the jurisdictional inquiry turns on the defendant's forum contacts "*at the time when the action was commenced.*" E.g., *Uzan v. Telsim Mobil Telekomunikasyon Hizmetleri A.S.*, 856 N.Y.S.2d 625, 626 (1st Dept 2008) (emphasis added; internal quotation marks and citation omitted) (holding that the trial court properly dismissed the plaintiff's suit for lack of general jurisdiction because the plaintiff "failed to show that as of the commencement of this action, [the defendant] was engaged in a continuous and systematic course of doing business in this state"); *Overseas Media*, 407 F. Supp. 2d at 568 (explaining that the "presence" required for general jurisdiction is a proxy for substance, continuity, regularity and permanence [of business presence in the forum] *at the time the action is brought*") (emphasis added) (quoting Weinstein, Korn & Miller, New York Civil Practice: CPLR ¶ 301.16 (2005)). On the merits, Alkem is far too removed from Breckenridge so as to be held responsible for its actions.

REDACTED

Ascend is a distributor located in New

Jersey.

REDACTED

That conduct is too fresh to be called "continuous and systematic" by the time the complaint was filed. This case is therefore unique in that there was no adequate history of connections, however indirect, to satisfy allegations of continuous and systematic

conduct at the time the complaint was filed in January 2011. This is because Alkem's connection to the U.S. as a whole is relatively new.

Moreover, and regardless of the timing issue, the sales and marketing contacts Plaintiffs allege are not sufficient to support general jurisdiction under the long line of New York cases rejecting such contacts as too far removed from the "continuous and systematic," domiciliary-like presence required for courts in the forum state to exercise their power over the defendant. *See, e.g., Simonson v. Int'l Bank*, 14 N.Y.2d 281, 285, 251 N.Y.S. 2d 427, 428 (1964) (explaining that the "doing business" test for corporate "presence" sufficient to establish general jurisdiction has its basis in the physical corporate presence theory that nineteenth century courts used as the litmus test for exercising general jurisdiction over corporate defendants.) For example, in *Parsons v. Kal Kan Food, Inc.*, 68 A.D.3d 1501, 892 N.Y.S.2d 246 (3d Dept 2009), the New York Court of Appeals held that a New Jersey warehouse and distribution facility that, like Alkem, was not itself registered in New York and had no offices, employees or real property there, did *not* do business in New York sufficient to support general jurisdiction under CPLR 301 even though: (1) it had New York customers whose goods were shipped to New York by an affiliated company; (2) the defendant advertised in New York via its website and brochures; and (3) the defendant's executive vice president came to New York once or twice a year to solicit sales and to call upon existing customers. *See id.* at 1502-03. As the court explained, these activities were *not* of "sufficient permanence and continuity" to constitute the defendant's "presence in New York" for general jurisdiction purposes. *Id.* at 1502 (internal quotations and citation omitted.)

The reasoning the Court of Appeals applied in *Parsons* is well settled and draws on a long line of cases reaching similar conclusions even where the defendant's contacts with New

York arise through affiliates or agents who have a closer relationship with the defendant than did the affiliated trucking company in *Parsons*. See *id.* at 1503. For example, in *Delagi v. Volkswagenwerk AG*, 29 N.Y.2d 426, 328 N.Y.S.2d 653 (1972), the court held that a German car manufacturer that had no facilities or employees in New York was *not* subject to general jurisdiction even though: (1) it advertised its products in the New York media; and (2) its cars were sold in New York by a network of franchiser dealers and an American wholesale distributor. As the court explained, the defendant's New York advertising was "mere solicitation" insufficient to support general jurisdiction, and the sales of its cars in New York were not enough of a "solicitation plus" factor as required in New York to conclude that the defendant was "doing business" here absent proof the defendant exercised control "so complete over its distributors that they ceased to have their own identities and were fairly viewed as merely "department[s] of the parent." *Id.* at 432. Similarly, the court in *Fremay, Inc. v. Modern Plastic Mach. Corp.*, 115 A.D.2d 235, 222 N.Y.S.2d 694 (1st Dept 1961), held that a defendant's shipment of goods to New York buyers on contracts made elsewhere did *not* qualify as doing business in New York for general jurisdiction purposes even though the defendant maintained a New York bank account and two of its officers resided in New York and engaged in incidental transactions in New York related to defendant's business. *Id.* at 700. Alkem's contacts fall far short of even these previously considered and rejected theories of personal jurisdiction as in *Parsons*, *Delagi* or *Fremay*.

It is black letter law that the presence of a subsidiary – even one in New York – does not establish the parent's presence in the state. See, e.g., *Jazini v. Nissan Motor Co.*, 148 F.3d 181, 184 (2d Cir. 1998). Alkem does not have a subsidiary here, and Plaintiffs do not allege otherwise. Alkem's connection to New York, REDACTED

REDACTED also falls short of other previously rejected theories of personal jurisdiction, including those based on the “agency” or “mere department” theories. *E.g.*, *Gallelli v. Crown Imports, LLC*, 701 F.Supp. 2d 263, 271 (E.D.N.Y. 2010) (finding no general jurisdiction even though foreign company supplied goods to subsidiary, had overlapping executive personnel, and referred to themselves as a “family”); *Tsegaye v. Impol Aluminum Corp.*, No. 01 Civ. 5943, 2003 WL 221743, at *4-*6 (S.D.N.Y. Jan. 30, 2003) (finding no general jurisdiction even though foreign company owned a subsidiary physically located in New York and in the same business of selling aluminum); *Pyramyd Stone Int’l Corp. v. Crosman Corp.*, No. 95 Civ 6665, 1997 WL 66778, at *4-*10 (S.D.N.Y. Feb. 18, 1997) (finding no general jurisdiction even though defendant purchased 98% of product from subsidiary, the subsidiary’s general manager reported directly to the parent, and the parent provided start-up capital contribution.) On the other hand, and showing just how extensive contacts must be in order to show general jurisdiction through any kind of indirect relationship, the *Beech* court found jurisdiction only where (1) the parent provided a \$400,000 no-interest “loan” to the subsidiary, (2) three of the subsidiary’s five-member board were the same as the parent’s, (3) the parent involved itself in the handling of difficult business transactions on behalf of the subsidiary, (4) the parent trained and instructed the subsidiary where to distribute, and (5) the subsidiary sold only the parent’s products and none others. *Volkswagernwerk Aktiengesellschaft v. Beech Aircraft Corp.*, 751 F.2d 117, 120-122 (2d Cir. 1984). Alkem’s relationship REDACTED is a far cry from that of the defendant in *Beech*.

The authorities that Plaintiffs recently cited in correspondence to the Court are not to the contrary. *See* Russo Dec., ¶ 6 (citing *LSI Indus. Inc. v. Hubbell Lighting, Inc.*, 232 F.3d 1369, 1375 (Fed. Cir. 2000); *Eli Lilly & Co. v. Sicor Pharms., Inc.* No. 1:06-CV-238, 2007 WL 1245882, at *6 (S.D. Ind., Apr. 27, 2007); 21 U.S.C. §355(j)(5)(C)(i)). Indeed, they simply

underscore the legal insufficiency of Plaintiffs' jurisdictional allegations here. In *Hubbell*, a case that arose under the Ohio, not New York, long arm statute, the defendant "did not mount a significant challenge to the court's exercise of [general] jurisdiction," which the court based not only on "millions of dollars of sales" in the forum, but also on the defendant's "significant amount of contacts with Ohio" through the *physical presence* of a "broad distributorship network" there. *Hubbell*, 232 F.3d at 1375. The unpublished Southern District of Indiana decision in *Sicor* is similarly inapposite (and regardless would have to be disregarded in favor of the controlling New York and Supreme Court precedents that govern this case). See *Eli Lilly*, 2007 WL 1245882, at *2, *5-6 (emphasizing that Sicor itself engaged in extensive "in-person" sales and marketing visits in the forum state, and had several employees whose compensation was at least 50% attributable to Sicor's continuous and systematic sales and marketing efforts there). Here, even if its connection to Alkem is pertinent, **REDACTED**

Finally, Plaintiffs' argument that declining general jurisdiction in New York would deprive Plaintiffs of their statutory "prerogative" of choosing the forum in which to bring their ANDA infringement suit (*see* Russo Dec., ¶ 6 at Pg. 3 n.3), is both inapposite and foreclosed by Supreme Court precedent. There is no statutory forum "prerogative," and instead an option for Plaintiffs to file suit within 45-days in a court of competent jurisdiction, should it choose to do so. If Plaintiffs choose to exercise that option, they are not excused from meeting state and Constitutional requirements for personal jurisdiction, and the suggestion that forum-shopping (particularly here where Plaintiffs have no real connection to New York) could somehow trump personal jurisdiction deserves no further discussion.

* * * * *

For all of the foregoing reasons, Plaintiffs have not, and cannot, meet their burden of proving that the requirements of New York's long arm statute have been met. Accordingly, it

is “unnecessary to determine whether the exercise of personal jurisdiction would comport with federal constitutional standards of due process...since a statutory basis for jurisdiction has not been established.” *Swindell v. Florida E. Coast Ry.*, 42 F. Supp. 2d 320, 326 (S.D.N.Y. 1999), *aff’d*, 201 F.3d 432 (2d Cir. 1999) (internal citations omitted). That said, the exercise of personal jurisdiction over Alkem would also fail to satisfy due process.

III. THE EXERCISE OF PERSONAL JURISDICTION WOULD VIOLATE DUE PROCESS

Because the “reach of New York’s long-arm statute . . . does *not* coincide with the limits of the Due Process Clause,” the arguments in this section would preclude jurisdiction even if the long-arm statute could be construed to encompass Alkem. *Best Van Lines, Inc. v. Walker*, 490 F.3d 239, 244 (2d Cir. 2007) (emphasis added) (explaining that the differences between the long-arm and due process inquiries may cause the jurisdictional analysis to “involve two separate inquiries, one statutory and one constitutional.”)

“The Due Process Clause of the Fourteenth Amendment operates to limit the power of a State to assert *in personam* jurisdiction over a nonresident defendant.” *Helicopteros Nacionales de Colombia v. Hall*, 466 U.S. 408, 413-14 (1984) (citing *Pennoyer v. Neff*, 95 U.S. 714 (1878).) Due process is satisfied when personal jurisdiction is asserted over a nonresident corporate defendant that has “certain minimum contacts with [the forum] such that the maintenance of the suit does not offend ‘traditional notions of fair play and substantial justice’.” *Int’l Shoe Co. v. Washington*, 326 U.S. 310, 316 (1945) (internal quotation marks and citation omitted). This test is met, and personal jurisdiction comports with the Constitution, where the plaintiff can establish that “the defendant purposely avail[ed] itself of the privilege of conducting activities within the forum State,” *Hanson v. Denckla*, 357 U.S. 235, 253 (1958), such that the defendant could “reasonably anticipate being haled into court there.” *World-Wide Volkswagen v. Woodson*, 444

U.S. 286, 297 (1980). It is critical to consider, however, that the forum contacts necessary to establish “purposeful availment” differ based on whether the personal jurisdiction asserted is specific or general.

As noted, specific jurisdiction exists when a “controversy is related to or ‘arises out of’ the defendant’s contacts with the forum,” *Helicopteros*, 466 U.S. at 414, because in such circumstances the “‘relationship among the defendant, the forum, *and the litigation*’ is the essential foundation of *in personam* jurisdiction.” *Id.* (emphasis added) (quoting *Shaffer v. Heitner*, 433 U.S. 186, 204 (1977)). In contrast, where a plaintiff invokes general jurisdiction because his “cause of action does *not* arise out of or relate to the foreign corporation’s activities in the forum State,” due process is satisfied only where the plaintiff can show “sufficient contacts between the State and the foreign corporation” that rise to the level of “the kind of *continuous and systematic general business contacts*” that historically established a domiciliary-like “presence” in the forum. *Id.* at 414, 416 (emphasis added). As controlling precedents (and even the non-binding decisions Plaintiffs cite, *see Sicor*, 2007 WL 1245882, at *5) emphasize, this test for general jurisdiction is “considerably more demanding” than the test for specific jurisdiction. *See, e.g., Helicopteros; Metropolitan Life, supra.* The reason, again, is that a finding of general jurisdiction does not limit the forum court’s authority over the defendant to a particular case, but instead represents a conclusion that the defendant has such a strong presence in the forum that its courts should be able to exercise jurisdiction over the defendant in any case arising out of the defendant’s actions anywhere in the world. Alkem’s conduct in India, and its relationships with companies in Florida (Breckenridge) or New Jersey (Ascend) are not “presence” in New York.

The contacts that Plaintiffs allege Alkem has with New York, even as supplemented by all the recent discovery Plaintiffs have taken, plainly do not satisfy the due process requirements

for general jurisdiction. The purposeful availment theory espoused by Plaintiffs has been strictly limited to cases involving specific jurisdiction. *See Republic of Argentina v. Weltover, Inc.*, 504 U.S. 607, 609-610, 619-620 (1992); *Asahi Metal Indus., Co. v. Superior Court of CA, Solano County*, 480 U.S. 102, 105-106 (1987); *Burger King Corp. v. Rudzewicz*, 471 U.S. 462, 472-473 & n.15 (1985); *Keeton v Hustler Magazine*, 465 U.S. 770, 774, 780 (1984) *World-Wide Volkswagen*, 444 U.S. at 288, 297; *Kulko v Superior Court of CA In and For City and County of San Francisco*, 436 U.S. 84, 86, 94 (1978); *Shaffer v. Heitner*, 433 U.S. 186, 213-216 (1977); *Hanson v Denckla*, 357 U.S. 235, 238, 253 (1958). This is not a specific jurisdiction case.

As noted, the Fourteenth Amendment's Due Process Clause limits "the power of a state court to exert personal jurisdiction over a nonresident defendant," *Asahi Metal*, 480 U.S. at 108. These limits serve two important, and related, goals. They protect a defendant's "liberty interest in not being subject to the binding judgments of a forum with which he has established no meaningful contacts, ties, or relations." *Burger King*, 471 U.S. at 471-72. And they bring "a degree of predictability to the legal system that allows potential defendants to structure their primary conduct with some minimum assurance as to where that conduct will and will not render them liable to suit." *World-Wide Volkswagen*, 444 U.S. at 297. These goals are typically satisfied where a corporation "'delivers its products into the stream of commerce with the expectation that they will be purchased by consumers in the forum State' and those products subsequently injure forum consumers." *Burger King*, 471 U.S. at 473 (emphasis added) (quoting *Volkswagen*, 444 U.S. at 298). In such cases, the forum-based injury can provide a sufficient nexus between the forum and a defendant that purposefully directed the specific allegedly culpable product there to support *specific* jurisdiction over the defendant. *See, e.g., Burger King*, 471 U.S. at 472 (explaining that the Due Process Clause's "fair warning requirement is satisfied

if the defendant has purposefully directed his activities at residents of the forum *and the litigation results from alleged injuries that arise out of or relate to those activities*”) (emphasis added.)

The Court’s general jurisdiction cases, by contrast, require the much more demanding showing that a foreign corporation “ha[s] been carrying on in the [forum] a *continuous and systematic . . . part of its general business*.” *Helicopteros*, 466 U.S. at 415 (quoting *Perkins*, 342 U.S. at 438) (emphasis added). The facts alone establish that Alkem’s contacts with New York fall well short of this mark. In *Perkins*, the Court held that Ohio courts could exercise general jurisdiction over the defendant (a Philippines mining company) consistent with due process because at the time the suit was filed: (1) the company’s president had relocated to Ohio where he carried on the company’s business from a physical office; (2) the Ohio office contained the company’s files, records, and payroll documents; and (3) the company maintained employees, held directors meetings, made policy decisions, and transacted business through Ohio-based bank accounts. *See id.* at 448. Based on this long list of physical and substantive contacts with the State, the Court concluded that the defendant had “carried on in Ohio a continuous and systematic supervision of” its general business. *Id.* This case involves no such contacts, and indeed involves far fewer forum connections than *Helicopteros*, in which the Supreme Court held that the exercise of general jurisdiction would violate due process. *See* 466 U.S. at 416.

In *Helicopteros*, the plaintiff sued a foreign defendant for damages arising out of fatal helicopter crash in Peru. The plaintiff asserted that the Texas courts had general jurisdiction over the defendant because its CEO had physically visited Texas to negotiate contracts, it had purchased the majority of its helicopters, equipment, and training services from a Texas-based manufacturer, and it had sent its personnel to the Texas manufacturer’s Fort Worth facilities for

training. *See id.* at 416. The Supreme Court concluded that these contacts did *not* “constitute the kind of continuous and systematic general business contacts . . . found to exist in *Perkins*” and necessary to satisfy due process because, among other things, forum-based sales transactions and “related trips” do not establish the defendant as having the domiciliary-like state presence required to support general jurisdiction. *Id.*

Plaintiffs’ theory of personal jurisdiction does not satisfy due process. The Court’s decisions in *Helicopteros* and *Perkins* make clear that the “continuous and systematic business contacts” required for the constitutional exercise of jurisdiction require far more than indirect contacts with New York, and the Court’s decisions in other general jurisdiction cases (notably *Keeton*, which was argued the same day as *Helicopteros*) prevent Plaintiffs from trying to circumvent this conclusion by asserting that some Alkem products may end up in New York through REDACTED. As the Court explained in *Keeton*, a “defendant’s contacts with the forum State must be assessed *individually*,” and even “jurisdiction over a parent corporation [does not] automatically establish jurisdiction over a wholly-owned subsidiary.”² 465 U.S. at 781 n.13 (emphasis added). This reasoning reflects the principle that, for due process purposes as for long arm purposes under New York law, *see supra* Part II.B, it is *only* where: (1) a parent exercises control over a subsidiary so complete that the subsidiary lacks “any semblance of individual identity,” *see, e.g.*, 4 Wright & Miller §1069.4, at 174 (citing cases); and (2) the subsidiary’s conduct itself rises to the level of the “continuous and systematic business presence” required for general jurisdiction, *see, e.g. Helicopteros; Keeton*, that the affiliation

² Here, the situation would be the reverse, and thus much harder to justify, if Plaintiffs attempt to argue that potential jurisdiction REDACTED should somehow result in general jurisdiction over Alkem.

between the two entities can be used to bolster the case for general jurisdiction over the parent. Plaintiffs do not, and cannot, allege any such facts here.

For the reasons above, the New York contacts Plaintiffs might assert, even as developed in discovery, do not constitute the kind of “continuous and systematic” business contacts necessary to establish that the exercise of general jurisdiction in this case would comport with due process. And even if one could force such a description on the purported activity, doing so would not remedy the constitutional problem with Plaintiffs’ jurisdictional claim because asserting general jurisdiction over Alkem would plainly violate the “fair play” and “reasonable” aspects of the constitutional inquiry in two fundamental respects. It would collapse the distinction between general and specific jurisdiction in a way that threatens to render the latter superfluous by subjecting defendants to general jurisdiction in every State in which their products end up through the “stream of commerce.” And in so doing, it would destroy the predictability and certainty that decades of precedent applying those distinctions have brought to the law in policing the limits the Fourteenth Amendment imposes on suits just like this one. *World-Wide Volkswagen*, 444 U.S. at 297. It would be unconstitutional to require Alkem to be haled into court here.

IV. **Even if Plaintiffs Could Establish a Valid Jurisdictional Basis for This Suit, Which They Cannot, The Suit Would Warrant Transfer to Illinois Under the Venue Statute**

Plaintiffs’ inability to establish personal jurisdiction over Alkem compels dismissal of this case. But even if Plaintiffs could somehow establish jurisdiction, the case could not remain here consistent with the venue statute. Plaintiffs have already filed a related action in the State of Illinois, which is where Alkem could have foreseen a litigation as to this particular ANDA submission because Illinois is where Alkem named an agent for service of process on matters relating to the ANDA. All the other factors set forth in 28 U.S.C. § 1404(a) would favor transfer

there. Further, Alkem is prepared to answer the Illinois complaint and will not challenge personal jurisdiction in that action. The court should therefore dismiss or in the alternative transfer this case to Illinois in the unlikely event that Plaintiffs are able to identify a proper jurisdictional basis for this action. *See generally* 28 U.S.C. § 1406(a).

CONCLUSION

For the foregoing reasons, Alkem respectfully requests that the Court grant its motion to dismiss Plaintiffs' complaint, for attorney fees for having to bring this motion, and for any other relief the Court deems just and appropriate.

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Respectfully submitted,

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